PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	3 JUN 2005
Applicant's or agent's file reference 12572860	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/AU2005/000238	23 February 2005	24 February 2004

Applicant

NATBIO PTY LTD et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Alistair Bestow Telephone No. (02) 6283 2450

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 12572860	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/AU2005/000238	International filing date *(day/month/year)* 23 February 2005	Priority date *(day/month/year)* 24 February 2004

International Patent Classification (IPC) or national classification and IPC

Int. Cl.

A23J 3/14 (2006.01) *C12N 9/50* (2006.01)

Applicant

NATBIO PTY LTD et al

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of **4** sheets, as follows:
      - [ ] sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      - [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

[X]	Box No. I	Basis of the report
[ ]	Box No. II	Priority
[X]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[X]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[ ]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[ ]	Box No. VIII	Certain observations on the international application

Date of submission of the demand 23 December 2005	Date of completion of this report 06 June 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **Alistair Bestow** Telephone No. (02) 6283 2450

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2005/000238

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

[X] The international application in the language in which it was filed

[ ] A translation of the international application into , which is the language of a translation furnished for the purposes of:

[ ] international search (under Rules 12.3(a) and 23.1 (b))

[ ] publication of the international application (under Rule 12.4(a))

[ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

[ ] the international application as originally filed/furnished

[X] the description:

pages **1 - 81** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

[X] the claims:

pages as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* **82 - 85** received by this Authority on **24 May 2006** with the letter of 24 May 2006.
pages* received by this Authority on with the letter of

[X] the drawings:

pages **1/5 – 5/5** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

[X] a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

4. [ ] This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2005/000238

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos: **7, 13-18, 32-34 (complete), 22 to 24 (partial)**

because:

☐ the said international application, or the said claims Nos.
relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos.
are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos.
are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*

☒ no international search report has been established for said claim Nos. **7, 13-18, 32-34 (complete), 22 to 24 (partial)**

☐ A meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ Furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ Furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ Pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ A meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	**1-6, 8-12, 19-21, 25-31 (complete), 22-24 (partial)**	**YES**
	Claims		**NO**
Inventive step (IS)	Claims	**1-6, 8-12, 19-21, 25-28 (complete), 22-24 (partial)**	**YES**
	Claims	**29 - 31**	**NO**
Industrial applicability (IA)	Claims	**1 - 6, 8 - 12, 19 - 31**	**YES**
	Claims		**NO**

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 Garden of Life FYI™ http://www.nuvobody.com/pages/products/fyi.aspx
D3 Fresh Ginger makes better meat tenderizer.
http://www.realcities.com/mld/twincities/living/7949674.htm
D4 Swelling http://www.mothernature.com/Library/bookshelf/Books/41/111.cfm
D5 THOMPSON, E. H., et. al. (1973) *Journal of Food Science* 38:652-5.
D6 LEE, Y. B. et. al. (1986) *Journal of Food Science*. 51(6):1558-9.
D7 Herb Facts www.herbnet.com/Herb+Uses_FGH.htm
D8 Ginger http://www.innvista.com/health/herbs/ginger.htm

Novelty (N) and Inventive Step (IS) claims 29 to 31

While D1, D4, D7 and D8 disclose the use of Zingibain to treat inflammation, it is agreed that they do not make a specific reference to the treatment of the particular diseases noted in claims 29 – 31. The treatment of a selection of a particular inflammatory disease however, from amongst a range of inflammatory diseases is however not inventive. A person skilled in the art, wanting to treat the diseases in the claimed manner, knowing that these diseases are inflammatory diseases, would find it obvious to use zingibain in the manner claimed, in view of any one of D1, D4, D7 and D8. Therefore claims 29 – 31 lack an inventive step.

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limit:

   ☐ restricted the claims

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ neither restricted the claims nor paid additional fees

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

   The separate groups of invention are:

   - Claims 1 to 6, 8 to 12 and 19 to 21 (completely) and claims and 22 to 24 (partially) are directed to the use of Zingibain to treat food to reduce or remove components which are the cause of food intolerance.
   - Claims 25 to 28 (complete) are to the use of Zingibain to treat food intolerance in a subject involving administering Zingibain to the subject.
   - Claims 29 to 31 (complete) are to the use of Zingibain to treat inflammatory disease.

   (continued in Supplemental Box)

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:

   ☐ complied with.

   ☐ not complied with for the following reasons:

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. **1-6, 8-12, 19-21, 25-31 (complete), 22-24 (partial)**

Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:

   a. type of material

      [X] a sequence listing

      [X] table(s) related to the sequence listing

   b. format of material

      [X] on paper

      [ ] in electronic form

   c. time of filing/furnishing

      [X] contained in the international application as filed

      [ ] filed together with the international application in electronic form

      [ ] furnished subsequently to this Authority for the purposes of search and/or examination

      [ ] received by this Authority as an amendment* on

2. [ ] In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

* *If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."*

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of IV:

- Claim 32 (complete) is to the use of Zingibain to treat cancer.
- Claim 7 (complete) is to the use of Zingibain to increase efficiency of alcohol production from a cereal.
- Claims 13 to 16 (complete) and claims 22 to 24 (partially) are to methods of increasing the percentage of water content in a food through treating the food with Zingibain.
- Claim 33 (complete) is to the use of Zingibain to cleave prion proteins in meat products.
- Claim 34 (complete) is to the use of Zingibain in cell harvesting to cleave fibrinogen.

The common feature of all the inventions is Zingibain. However this is known in the prior art, as is various uses of Zingibain. See, for example the following documents cited in the International Search Report:

Fresh Ginger makes better meat tenderizer. http://www.realcities.com/mld/twincities/living/7949674.htm
Swelling http://www.mothernature.com/Library/bookshelf/Books/41/111.cfm
THOMPSON, E. H., et. al. (1973) Journal of Food Science 38:652-5.
LEE, Y. B. et. al. (1986) Journal of Food Science. 51(6):1558-9.
Herb Facts www.herbnet.com/Herb+Uses_FGH.htm
Ginger http://www.innvista.com/health/herbs/ginger.htm

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CLAIMS:

1. Use of *Zingibain* in the treatment of food in an amount effective to reduce or remove food intolerance in a subject.

2. Use according to Claim 1 wherein the amount is further effective to increase the palatability of food.

3. Use according to Claim 1 or 2, wherein the food is a cereal, a legume, a nut or dairy product containing food.

4. Use according to Claim 2 or 3, wherein the cereal is wheat, oats, barley, rye, sorghum, or corn.

5. Use according to Claim 1 or 2, wherein the food is a bakery product, breakfast cereal, pasta or snack food.

6. Use according to Claim 5, wherein the bakery product is selected from the list comprising: breads, cakes, muffins, crumpets, English muffins, pizza bases, biscuits, cookies, doughnuts, scones, pancakes, pikelets and buns.

7. Use of *Zingibain* in the production of alcohol from cereal in an amount effective to increase the efficiency of said production.

8. Use according to any one of Claims 1 to 4, wherein the food is an animal food product.

9. A method for preparing a bakery product with cleaved gluten comprising the steps of:

a) mixing ingredients of the bakery product with an improver, said improver comprising *Zingibain* in an amount effective to cleave gluten, with further

ingredients of the bakery product, and forming a dough or mixture or batter;

b) if required, allowing the dough or mixture or batter to rest; and

c) comminuting the dough if required, shaping and baking the dough or mixture or batter to form the bakery product.

10. The method according to Claim 9 wherein the bakery product is selected from the list comprising: breads, cakes, muffins, crumpets, English muffins, pizza bases, breakfast cereals, biscuits, cookies, doughnuts, scones, pancakes, pikelets and buns.

11. A bakery product produced according to any one of Claims 9 or 10.

12. A bakery product according to Claim 10 wherein the bakery product is selected from the list comprising: breads, cakes, muffins, crumpets, English muffins, pizza bases, biscuits, cookies, doughnuts, scones, pancakes, pikelets and buns.

13. A food or food component treated with or comprising an amount of *Zingibain* effective to increase the percentage water content in an amount of from about 1% to about 5%.

14. A food according to Claim 13, wherein the food is a cereal containing food or snack food.

15. A food according to Claim 13, wherein the food is pasta.

16. A food according to Claim 14, wherein the cereal containing food is a bakery product.

17. A food according to Claim 16, wherein the bakery product is selected from the group comprising bread, cake, muffin, crumpet, English muffin, pizza base, biscuits, cookies, doughnuts, scones, pancakes, pikelets and buns.

18. A food according to Claim 16, wherein the bakery product is bread, wherein the bread has an improved texture and/or crust.

19. A food or food component treated with or comprising an amount of *Zingibain* effective to reduce or remove food intolerance in a subject.

20. A food component according to Claim 19 wherein the food component is selected from the group comprising flour and whole grains.

21. A food according to Claim 19, wherein the food is an animal food product.

22. A food according to any one of Claims 13 to 21, wherein the food has reduced allergenicity to the relevant population in comparison to a corresponding untreated food.

23. A food according to any one of Claims 13 to 21, wherein the food or component has an increased shelf-life in comparison to a food or component not so treated.

24. A food according to any one of Claims 13 to 21, wherein the food has increased nutritional value and/or increased absorption in comparison to a food not so treated.

25. Use of *Zingibain* for the manufacture of a medicament in the treatment of food intolerance in a subject.

26. Use according to Claim 25, wherein the food intolerance is gluten intolerance.

27. Use according to Claim 26, wherein the gluten intolerance is Coeliac disease.

28. A method of treating gluten intolerance or Coeliac disease comprising administering to a person a therapeutically effective amount of *Zingibain*.

29. Use of *Zingibain* in the manufacture of a medicament for the treatment of an

inflammatory disease selected from the group consisting of gluten intolerance, such as Coeliac disease, ulcerative colitis, inflammatory bowel disease and/or Crohn's disease.

30. Use of *Zingibain* in the manufacture of a medicament for the treatment of an inflammatory disease selected from the group consisting of gluten intolerance, such as Coeliac disease, ulcerative colitis, inflammatory bowel disease Crohn's disease or infection by a pathogenic agent.

31. A method according to Claim 30, when the pathogenic agent is selected from the group comprising viruses, bacteria and parasites.

32. Use of *Zingibain* in the manufacture of a medicament for the treatment of cancer.

33. Use of *Zingibain* in the treatment of meat or meat derived products in an amount effective to cleave prion proteins.

34. Use of *Zingibain* in cell harvesting in an amount effective to cleave fibrinogen.